MEDICAL CABLES™

JUN 2 2 2001

1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-3469•(800) 828-1599•FAX (714) 545-7212

510(k) Summary

Contact Person: Robert Hilman, Quality / Regulatory Affairs
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Date Prepared: March, 2001

Product Classification: Product Classification: Class II – Transducers for use with perinatal monitoring systems as accessories as described in Title 21, Part 884, Subpart C, Classification # 85 HGL, Regulation number Obstetrical Ultrasonic Transducer and Accessories and in Title 21, Part 884, Subpart C, Classification # 85 HFM, Regulation number 884.2720 External Uterine Contraction Monitor and Accessories.

Trade Name: Medical Cables Inc. Transducers for Fetal Ultrasonic and Tokodynamometer Monitoring.

Common Name: Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring

Predicate devices: This product is substantially equivalent to the following legally marketed Devices: a. Corometrics 116 (5700 & 2260), 510(k) # K891595 by GE Marquette Medical Systems
b. Epic's transducer, 510(k) # 992811 by Epic Medical Equipment Services.

Description: Medical Cables Inc. Transducers for Fetal Ultrasound and Tokodynamometer Monitoring are direct replacements for similar transducers manufactured by GE Marquette Medical Systems and Epic Medical Equipment Services. A Transducer employing ultrasound Doppler Shift Technology is used for the detection of Fetal Heart Rate to ascertain fetal condition during labor and a Tokodynamometer Transducer, which actually is a strain gauge, is used to evaluate and measure the duration, frequency, and relative pressure of uterine contractions during labor.

Intended Use: Medical Cables Inc. Transducers for Fetal Ultrasound and Tokodynamometer Monitoring are intended to be used only as direct replacement accessories for appropriate Perinatal Monitoring Systems showing the graphical relationship between maternal labor and fetal heart rate.

Performance Standards : Medical Cables Inc. has declared to conform to consensus performance standards concerning Electrical / Electromagnetic Compatibility / Mechanical / Efficacy / Safety and Biocompatibility aspects of the product.

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MEDICAL CABLES PRODUCT COMPARISON TABLE TO PREDICATE DEVICES

	Medical Cables	GE Marquette 116 (5700 & 2260)	Epic Medical Transducer
Intended use	To detect, measure and record fetal heart rate and to measure the duration, rate and relative pressure of uterine contractions during labor.	SAME	SAME
Target patient population	Gravid patients especially during labor.	SAME	SAME
Patient usage	Reusable	SAME	SAME
Sterility	Non Sterile	SAME	SAME
Transducer cable length	Various specified standard lengths	SAME	SAME
Wire material		SAME	SAME
Connector design	Transducers are color coded and design-ed to fit into the appropriate monitoring system.	SAME	SAME
Patient attachments	These devices attach to the patient with elastic belts strapped on the patient.	SAME	SAME
Accessories	Transducer belts and Ultrasonic Gel.	SAME	SAME
Anatomical sites	The Tocodynamometer transducer is placed on the patient's abdomen over the fundus area of the uterus, and the ultra-sound transducer is placed on the patient's abdomen and aimed at the fetal heart.	SAME	SAME
FHR range.	As to monitor system specifications.	SAME	SAME
Uterine activity range.	As to monitor system specifications	SAME	SAME
Operational Characteristics	Medical Cables Transducer to be Pulsed Doppler - SAME	Coro 5700 = Pulsed Doppler	EFU400 –25 = Pulsed Doppler
Specifications(Ultrasound Center Frequency)	Medical Cables Transducer to be At 1.151 Mhz - SAME	Coro 5700 = 1.151 Mhz	EFU400-25= 1.151 Mhz
Acoustic Output	Medical Cables Transducer to emit <20mW/cm²avg.-SAME	<20mW/cm²avg.	<20mW/cm²avg

CONCLUSION:

As described in 9.1, Medical Cables has declared conformity to consensus performance standards and substantial equivalence of product to the following predicate devices manufacturers:

Predicate Manufacturer	Predicate Device	510(k) Number
GE Marquette Medical systems	Corometrics 116(5700 & 2260)	K891595
Epic Medical Equipment Services	Epic's Transducers	K992811

This 510(k) summary of safety and effectiveness information of product is submitted in accordance with the requirements of 21 CFR § 807.92(c).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Mr. Christopher Fontana
Vice President
Medical Cables™, Inc.
1340 Logan Avenue
COSTA MESA CA 92626

Re: K010920
Medical Cables, Inc. Transducers for Fetal Ultrasonic and Tokodynamometer Monitoring
Dated: March 27, 2001
Received: March 27, 2001
Regulatory Class: II
21 CFR §884.2660/Procode: 85 HEL
21 CFR §884.2720/Procode: 85 HFM

Dear Mr. Fontana:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

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STATEMENT OF INDICATIONS FOR USE

Medical Cables, Inc. Transducers are for use with perinatology monitoring systems by qualified personnel in the field of Obstetrics and Gynecology for both Normal and Pathologic conditions. Medical Cables, Inc. Ultrasound and Tocodynamometer transducers are the accessory components that are in direct patient contact and constitute essential accessory components of a Perinatal Monitoring System. The ultrasound sound transducer detects and evaluates fetal heart rate during uterine contractions using Doppler Shift Technology and the Tokodynamometer transducer detects uterine contractions using a strain gauge. Transducers are to provide a means of sensing and functioning as a connection for signals to pass through from the patient to the Monitoring or Recording Device. No other usage is intended for the transducers.

Christopher Fontana

27th March, 2001

Prescription Use √

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010920